UW Health: Study finds patients with inflammatory bowel disease have immune response to COVID-19 vaccine; expands enrollment

Posted on Wednesday, Sep 8, 2021

MADISON, Wis. – The University of Wisconsin School of Medicine and Public Health is expanding a study investigating the efficacy of the COVID-19 vaccine for people who have inflammatory bowel disease (IBD).

Enrollment for the study, called HERCULES, began in April 2021. Participants were people who have IBD and either recently got the COVID-19 vaccine or planned to get vaccinated soon. Now, the study is looking to enroll about 100 more participants with IBD who have gotten the COVID-19 vaccine third dose or plan to soon.

Patients with IBD are often treated with immunosuppressant drugs to treat and manage their conditions. Studies have shown that the majority of medications used to treat IBD, such as biologic drugs that act on specific immune system responses relevant to the disease, don’t increase the risk for severe COVID-19, but generally immunosuppressive medications like corticosteroids are associated with a higher risk for severe COVID-19.

So far, results from the HERCULES study show 97% of study participants with IBD mounted an immune response with COVID-19 vaccines. In light of these results, researchers are now expanding study enrollment.

The study originally enrolled 122 participants, and researchers found antibodies in 118 participants, according to Dr. Freddy Caldera, gastroenterologist, UW Health,

and associate professor of medicine at the UW School of Medicine and Public Health. Antibodies against the virus that causes COVID-19 help the immune system fight off the infection and are measured by testing blood samples, according to Caldera.

“Most of my IBD patients are on immune modifying therapy, but they are also often younger and don’t have any comorbidities, so we expected them to mount a response, but we needed the data to be sure,” said Caldera. “With the latest CDC guidance for those who are immunocompromised, we now need to expand this study to see how the third dose impacts antibody levels and other markers of an immune response for the patients.”

Recent guidance from the CDC says that those who are immunocompromised should get a third dose of the Pfizer or Moderna 2-dose COVID-19 vaccine. The CDC reviewed studies that evaluated immune response in transplant or cancer found that these populations were less likely to mount an immune response to the vaccine.

However, Caldera is following the recommendation from the CDC that his patients with IBD also receive a third dose of the MRNA vaccine.

“Studies like ours and others are important so we can determine what immune markers will protect us from severe COVID, a ‘correlate of immunity,’ but no one has that answer yet.”

said Caldera. “We are proud that the University of Wisconsin is one of the few centers in the country looking to find this answer for patients with IBD. We are also evaluating long term antibody response, T cell activity and other immune markers.”

IBD affects approximately 1.3% adults in the United States and is a term for two conditions (Crohn’s disease and ulcerative colitis) that are characterized by chronic inflammation of the gastrointestinal tract. The inflammation can cause persistent diarrhea, abdominal pain, rectal bleeding and/or weight loss. IBD is different from irritable bowel syndrome (IBS). While IBS impacts quality of life, it does not have the significant complications of IBD.

The study takes place at University Hospital in Madison and will involve blood draws from patients to examine the immune system response after vaccination by evaluating antibodies and T cells.

According to Caldera, four million Americans have IBD and UW Health treats 1,500-1,800 patients living with IBD every year.

The study is run by the UW Clinical Research Office and funded by the American College of Gastroenterology and Takeda Pharmaceuticals.

If you are interested in participating in the study, please contact the study team at the UW Clinical Research Office (608) 262-1632 or email djgriese@clinicaltrials.wisc.-edu

A recorded interview with Caldera is available and he will also be available for interviews.